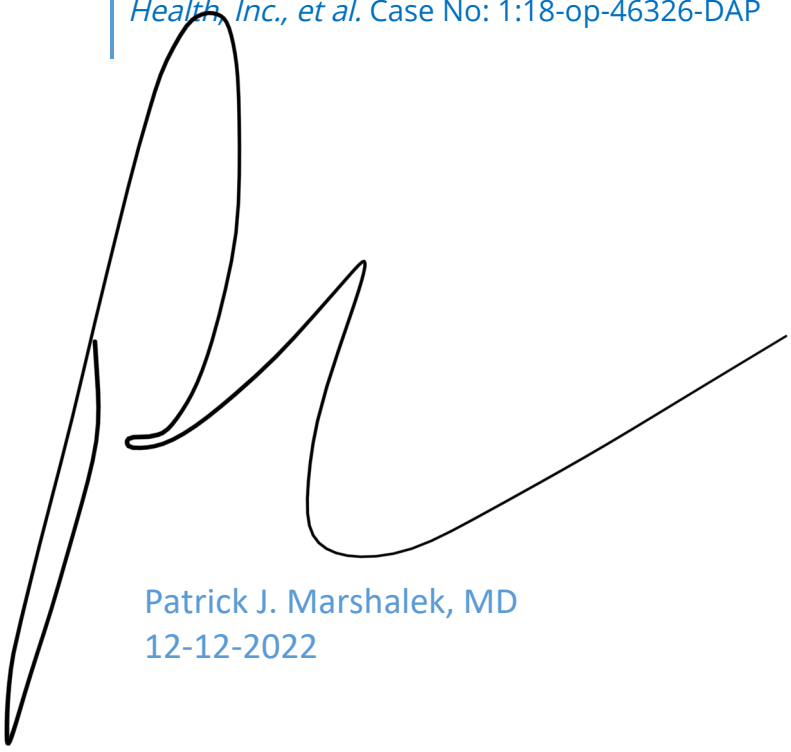
EXHIBIT C

Report and Opinions of Patrick J. Marshalek, MD

Montgomery County Board of County Commissioners, et al. v. Cardinal Health, Inc., et al. Case No: 1:18-op-46326-DAP



Patrick J. Marshalek, MD
12-12-2022

BACKGROUND AND QUALIFICATIONS

Patrick J. Marshalek, MD, is a Psychiatrist who practices at the Rockefeller Neuroscience Institute at WVU Medicine in Morgantown, West Virginia. Dr. Marshalek is board certified in Psychiatry (American Board of Psychiatry and Neurology) and Addiction Medicine (American Board of Preventative Medicine). He provides a variety of inpatient, outpatient, consultative and procedural services. He has helped with the development and implementation of a variety of innovative service lines. While serving as co-medical director for pain management, he assisted with the successful launch of the WVU Medicine Center for Integrative Pain Management. Shortly thereafter, he began serving as the medical director for Chestnut Ridge Center overseeing expansion of multiple service lines and ultimately transitioning to the role of Vice Chair of Inpatient Clinical Services. Currently, he is serving as the Division Chief for Addiction Services.

In addition to his clinical and administrative practice, Dr. Marshalek is an Associate Professor in the WVU School of Medicine's Department of Behavioral Medicine and Psychiatry, Department of Anesthesiology and Department of Neuroscience.

Dr. Marshalek's other relevant qualifications, publications, and experiences are detailed in his attached *curriculum vitae*.

OPINIONS OF PATRICK J. MARSHALEK, MD

Healthcare can be delivered in a wide variety of ways, and the way in which it is delivered can have a large impact on the outcomes. The delivery system in the United States involves a complex network of entities all working together to ensure that care is provided in a safe and effective manner. This complex network includes front line clinicians, allied health professions, and administrators with a variety of backgrounds ranging from financial to legal. It also includes federal, state, and commercial payors. Various regulatory agencies, ranging from federal to state to local, also interface with the aforementioned stakeholders in order to ensure the delivery of safe and effective care.[1]

All delivery systems have inherit strengths and weaknesses, as well as various checks and balances. The system in the United States is known for having higher expenditures when compared to other countries and pharmaceutical costs account for around of 17 percent of overall expenditures.[2] This serves as the basis for a common criticism of our system as well as others—overreliance on prescription medications. This overreliance converged with a shift in the standard of care with respect to pain management. Pain was declared as the "fifth vital sign' by experts in the field and was to be "treated at all costs." This approach was widely promoted and adopted by many of the stakeholders in our system.[3] Aggressive marketing of prescription opioids by pharmaceutical manufacturers created a quick and easy fix, and the overall amounts of prescribed opioids rapidly increased until the true costs were realized.[4]

Many opioid prescriptions were written by clinicians practicing in busy outpatient settings, often juggling more than one condition in fifteen to thirty minute time slots. These clinicians used their prescriptive authority to write "orders" for opioids after assessing the patient. Their scope of practice allowed for this and this authority is unique to physicians (MD/DO) and advance practice professionals (PA/NP), when compared to other allied health professions.[5] Registration with the Drug Enforcement Agency is required in order to prescribe controlled substances and governs aspects of prescribing practices.[6]

Prescriptions for opioids were issued by providers trying to adhere to the new standards of care surrounding pain management. They were issued after a process known as informed consent occurred. Informed consent is essentially a discussion between the clinician and patient regarding the risks, benefits, and alternatives surrounding the proposed intervention for the condition being treated. It is necessary before procedures like surgery but also applies to medications.[7] Prescription opioids also had a FDA indication associated with their use. These prescriptions were typically issued inside the course of medical practice and for legitimate reasons.[8]

The prescriptions left the clinic setting and traveled to the pharmacy, where the pharmacist worked to fulfill the order. Pharmacists did so by utilizing their own unique scope of practice. Short of situations where there were questions about the order such as if it was incomplete, appeared to be forged, or there was a potentially serious interaction or allergy discovered, prescriptions were fulfilled. The pharmacists have the ability to call the doctor's office in the event of serious questions or concerns, but cannot do so for every prescription. Additionally, the pharmacists' scope of practice and situation downstream from the medical decision making and informed consent process prevent and limit their ability to question the legitimacy of prescriptions, and if they were ordered in the course of routine medical practice.

The push to use opioids to treat pain decreased as the costs of doing so were realized, with prescriptions beginning to decrease around 2011, around the time that the CDC declared an epidemic associated of prescription drug overdoses. Much of the costs were secondary to exacerbation of an ongoing addiction epidemic. Prescription opioids acted like fuel for this long burning fire—a fire that has previously burned throughat other point in history.. This fire is now fueled by illicit fentanyl and methamphetamine and is a fire that can burn through more than just substances as evidenced by process addictions.[9] [15]

The risks and benefits of opioids have been known for almost as long as they have been in use. However, our understanding of the risks has been limited due to challenges understanding, diagnosing and treating addiction. In the late 1800's, the Bayer Company marketed prescription heroin as a safe, non-addictive, and effective pain reliever. They went as far as to promote it as a cure for morphine addiction. The initial push to treat pain at all costs was related to previous under treatment, and many cited the suffering from that undertreated pain. Once the pendulum swung in the other direction, a different form of suffering was encountered.[10] Despite more knowledge of the risks, opioids remain necessary, remaining on the World Health Organizations list of essential medicines.[11]

Addiction remains an incredibly complex and challenging illness to diagnose and treat. A variety of genetic, biological, psychological and social aspect come into play in understanding addiction.[12] Many of the recent overdose deaths have been referred to as "deaths of despair," highlighting this complexity, and impact of socioeconomic factors.

Despite recent advances in the field, there is still much to learn. Complicating matters further, a stigma surrounds this condition more than other chronic diseases. Many look at it as simply a choice or a moral failing. The medical community struggled with this, as the generation of allied health professional practicing during peak opioid prescribing received limited medical training and education on the topic of addiction. Some attempts to understand and explain the disease of addiction have shifted the focus more towards particular substances instead of the relationship the user has with the substance at issue, often vilifying substances that can have both therapeutic and illicit or recreational uses. For example, opioids have been unnecessarily vilified and some have even suggested their prohibition for medical use. Prohibition of opioids has also proved problematic and has contributed to the stigma surrounding addiction, often leading to criminalization of behaviors connected to the illness, and incarceration of patients in cases where treatment would have been better, as demonstrated by the advent of drug courts and growing body of evidence supporting their use.[13]

The "gateway" theory, which proposes that the use of prescription opioids directly leads to use of illicit drugs, is unsubstantiated and controversial. This theory leaves one to believe that a substance is acting more like a communicable disease and once exposed to it, the disorder develops. This inappropriately shifts the focus on to a substance and away from the illness. Multiple substance have been studied for abuse potential and a common denominator is that not everyone exposed to the substance ends up developing a use disorder.[14]

The illness of addiction does not discriminate with respect to particular substances. Process or behavioral addictions can occur to things like gambling, shopping, sex and the internet. Addiction is a chronic relapsing and remitting illness, at risk of being activated by any number of substance and non-substances.[15]

The aforementioned challenges surrounding addiction converged with the challenges surrounding pain management as opioids were increasingly utilized. Pain can be viewed more as a symptom than a disease. Assessing pain as the fifth vital sign was often done on a 1-10 scale with 10 being the worst imaginable pain. As opposed to the objective nature of measurable vitals, this report was subjective in nature. An opioid prescription could make the number go down and if not, there were stronger and longer acting formulations a prescription away. A pitfall associated with symptom management is that a wide variety of possible etiologies could be fueling the subjective reports of pain. [9]

In addition to informed consent, the clinician with prescriptive authority bears the burden of maximizing the benefits and minimizing the risks of any proposed intervention. Appropriate opioid prescribing requires a thorough patient assessment, short and long-term treatment planning, close follow-up, and continued monitoring. All providers need to be aware of appropriate patient assessment and treatment planning, and the possibility of use disorder, diversion, and potentially dangerous behavioral responses to controlled substances.

The term pill mill has been used to describe as an illegal facility that resembles a pain management clinic. In this setting, opioids are prescribed for non-existent of exaggerated pain, cash is typically the form of payment, and prescriptions are typically directed to specific pharmacies.[16]

Unless directly connected to a pill mill or engaged in other illegal or fraudulent activities, the pharmacy and pharmacist are at a disadvantage with respect to determining if the opioid prescription was legitimate, written in good faith, inside the course of medical practice and within the scope of a prescriber. It is not within the scope of a pharmacist to assess, manage and oversee the treatment plan.. Pharmacists would not immediately know if proper screening, such as pill counts and urine drug screening, had occurred unless they called and spoke to every single prescriber, which would not allow prescribers enough time to manage their workflows.

There were unintended consequences associated with shifting our approach to treating pain at all costs. These are now well known and described. However, not long after the pendulum swung in that direction, an equal and opposite push began to swing things in the opposite direction. Associated with this push are another set of unintended consequences that are talked about less often. Caught in the middle of this is a large group of patients accustomed to pain management with opioid analgesia. Their pain related conditions were treated with opioids for many years. The management of this large group varied widely and contains those clearly in need of treatment for opioid use disorder, but also many who might appear have opioid use disorder due to simply developing physiological dependence to opioids. The term pain refugee had been introduced to describe the population impacted by the sudden and abrupt shift away from opioids.[17] The CDC even had to clarify their prior statements surrounding opioid prescribing, warning against abrupt discontinuation in patients on longer term or higher dose opioids as many prescribers suddenly stopped prescribing opioids to patients managed long term with high doses.[18]

The other unintended consequences are related to the wide net of blame cast upon the stakeholders, including manufacturers, distributors, pharmacies, pharmacists, prescribers and patients. Some stakeholders have been charged, pleaded guilty, sentenced or settled in cases where illegal, fraudulent and/or unethical behaviors occurred. Fear related to this wide net, has led many well-meaning medical providers to simply stop prescribing opioids, or move away from managing pain conditions, decreasing access to much needed care for those suffering from acute and chronic pain.[17] [19]

While much has been written about the role played by the prescription opioid manufacturers, distributors, pharmacies, pharmacists, prescribers and patients, less has been written on the role the federal government could have played. The decision surrounding the overall amount of opioid allowed to be manufactured each year is decided by the federal government. The federal government makes the decision regarding what schedule on which to place controlled substances. In 2014, the DEA changed the schedule of commonly prescribed combination production that contained hydrocodone and Tylenol from Schedule III to Schedule II. This limited the amount of refills essentially, but failed to address other similar combination products that were more commonly prescribed and did not make a dent in the number of opioids prescribed.[20]

FDA can require certain medications to have what are known as REMS (Risk Evaluation and Mitigation Strategies) which are drug safety programs. For example, clozapine has a REMS due to the risks of agranulocytosis, and s-ketamine nasal spray has a REMS due to risks related to misuse, diversion, and dissociation.[21]

In order to use buprenorphine to treat opioid use disorder, a prescriber must apply for a waiver from the DEA before a prescriber could utilize. A key component of the waiver application was training surrounding the medication and disorder it treated.[22]

Decreasing the overall amount of authorized opioids, REMS programs, or waiver requirement, all could have been applied or utilized by the federal government and would have been situated upstream from the manufacturers and far from the front line clinicians limiting the blanket of blame currently being cast upon a large group of health care professionals that were simply trying to adhere to shifting standards of care and practicing legally and ethically within their respective scopes of practice, attempting to deliver quality patient care.

Far upstream from the busy prescriber, pharmacist, and community pharmacy sat those with power and ability to limit the overall amount of prescriptions that ultimately contributed to the epidemic of overdose deaths.[23] The federal government could have limited the amount of opioids manufactured, changed how opioids were scheduled, changed the FDA indication of opioid use, used REMS programs or waiver requirements, or limited the manufacturers' ability to influence prescribing through marketing communications and other activities. To suggest that community pharmacies, or the pharmacists working for those community pharmacies, are responsible for the crisis of addiction is wrong.

I hold all the opinions expressed herein to a reasonable degree of scientific, medical, and professional certainty.

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PRIOR TESTIMONY

The following are all the cases in which I have provided testimony as expert at trial or deposition during the prior four years:

- United States v. Brizuela, N.D. W. Va.
- United States v. Brizuela & Naum, N.D. W. Va.
- United States v. Naum, N.D. W. Va.
- Hatcher v. B & K Pharmacies, Inc., Circuit Court of Mingo County, West Virginia

STATEMENT OF COMPENSATION

My hourly rate is $400 for report preparation and $500 for testimony. I am providing invoices for my services in connection with this report. I am not compensated based on the outcome of this matter nor the substance of my report.

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